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Does Whole Body Vibration Therapy Improve Balance in Patients With Type 2 Diabetes Mellitus?

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A SELECTIVE EVIDENCE BASED MEDICINE REVIEW

In Partial Fulfillment of the Requirements For

The Degree of Master of Science

In

Health Sciences – Physician Assistant

Department of Physician Assistant Studies
Philadelphia College of Osteopathic Medicine
Philadelphia, Pennsylvania

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ABSTRACT

OBJECTIVE: The objective of this selective EBM review is to determine whether or not whole body vibration (WBV) therapy improves balance in patients with type 2 diabetes mellitus (DM).

STUDY DESIGN: A review of three peer-reviewed studies published between 2013 and 2015.

DATA SOURCES: Two randomized controlled trials and one case series. Using PubMed and Google Scholar, studies were selected if they assessed the effects of whole body vibration therapy on improving balance in diabetic patients, and whether the outcomes were patient oriented.

OUTCOMES MEASURED: The outcome measured in this study was balance, which was assessed using the Timed Up And Go test.

RESULTS: The study conducted by Del Pozo-Cruz J et al. did not find a statistically significant relationship between the improvement of balance in type 2 DM and WBV therapy (p value= 0.273).⁷ However, two separate studies by Kodi Yoosefinejad A et al. found a statistically significant relationship between WBV therapy and an improvement in balance of those with type 2 DM (p values= 0.002 and 0.004).^{8,9}

CONCLUSIONS: The results of these studies are inconclusive, as two studies found a statistically significant relationship and the other did not. Further studies on a larger amount of subjects need to be conducted to determine if the results are generalizable.

KEY WORDS: Whole body vibration therapy, Type 2 diabetes mellitus.

INTRODUCTION

Diabetic neuropathy is a common complication of poorly controlled type 2 diabetes that can cause significant impairment to an individual. One of these negative effects is problems with balance and coordination, which can lead to falls and further injury.¹

Diabetes, specifically type 2, is extremely common in the United States, and neuropathy is the most common complication of diabetes. An estimated 10% of the US population is afflicted with diabetic neuropathy and that number is rapidly increasing.² The annual cost for the treatment of diabetic neuropathy is estimated to be between 4.3 and 12.7 billion dollars per year.³ On average, there are approximately 1.4 million office visits and 329,000 hospitalizations due to this condition and its complications.⁴ Medical professionals are still unclear about the specific pathophysiology that causes diabetes to lead to neuropathy. It is known that poorly controlled blood sugar and chronic hyperglycemia can lead to damage of the nerves. It is unknown, however, the exact mechanism for this nerve injury and what causes each specific type of neuropathy, whether it be autonomic, peripheral, or polyneuropathy.¹

It is important to try to prevent diabetic neuropathy before it occurs, and this is accomplished by adequate regulation of blood glucose through methods such as carbohydrate counting, oral medications, insulin, and frequent blood glucose self-checks. These measures can also help the condition from worsening once it develops. Medications can such as amitriptyline, duloxetine, pregabalin, and gabapentin are frequently prescribed to help reduce pain in established neuropathy, although like any medication, these are not without their side effects.⁵ Whole body vibration (WBV) therapy is a new technology that first started being implemented by physical therapists

and has become increasingly used to treat a variety of health conditions, including diabetic neuropathy. WBV therapy consists of a patient standing on a vibrating board for a specific duration a few times per week. The vibration from the board travels through the body and produces small, non-painful nerve impulses which stimulate the touch and vibration receptors in the dorsal horn of the spinal cord. It is hypothesized that since these vibration impulses are stronger than the pain impulses, it therefore masks those painful impulses and decreases the sensation of pain. This improves a patient's overall sensation and balance, therefore decreasing the risk of falls and improving overall quality of life.⁶ This paper evaluates three studies that measure the effectiveness of whole body vibration (WBV) therapy as a treatment for the loss of balance that can occur due to diabetic neuropathy.

OBJECTIVE

The objective of this selective EBM review is to determine whether or not whole body vibration therapy improves balance in patients with type 2 diabetes mellitus.

METHODS

Criteria used for selection of studies:

The population of interest includes patients with type 2 diabetes mellitus over the age of 18 who have mild to moderate diabetic neuropathy. The intervention of focus is whole body vibration therapy. The comparison group is patients with type 2 diabetes mellitus who did not receive whole body vibration therapy, and instead receiving no treatment. The outcome measured was balance, which was measured using the Timed Up And Go (TUG) test. The types of studies include two randomized controlled trials and one case series.

Table 1 - Demographics & Characteristics of Included Studies

Study	Type	# Pts	Age (yrs)	Inclusion criteria	Exclusion criteria	W/D	Interventions
Del Pozo-Cruz ⁷ (2013)	RCT	39	Control group- 66.80 +/- 10.83 Intervention group- 71.60 +/- 8.54	T2DM confirmed by provider using American Diabetes Association dx criteria	Pts w/ advanced CV, renal, or hepatic ds, diabetic retinopathy, nephropathy or neuropathy, insulin use, and orthopedic or other limitations that may interfere with participants' ability to exercise safely. HbA1c of >10%, pts receiving physical therapy	11	WBV therapy- 3x/wk for 12 wks
Kordi Yoosefinejad ⁸ (2015)	RCT	20	Control group- 57 +/- 1.5 Intervention group- 57 +/- 1.8	Hx of DM according to ADA guidelines or using oral hypoglycemic agent; HbA1C < 8.5%; BMI between 25-35; Michigan Diabetic Neuropathy Score between 13-29 (mild to moderate neuropathy) and age between 50-70 years.	epilepsy, cognitive disorders, knee or hip prosthesis, pacemaker and gall or bladder stones.	0	Whole body vibration therapy- 2x wk/ 6 wks
Kordi Yoosefinejad ⁹ (2014)	Case series	10	56 +/- 5.16	Hx of type 2 DM according to ADA guidelines or using oral hypoglycemic agent; HbA1C < 8.5%; BMI between 25-35; Michigan Diabetes Neuropathy Score between 13-29 (mild to moderate neuropathy), and age between 50-70 years.	none	0	One session of whole body vibration therapy

Data sources:

The key words for searching articles were “whole body vibration therapy and type 2 diabetes”. All articles were published in English, and all three articles were published data in journals. I researched Pubmed and Google Scholar databases in order to find studies. Articles were selected based on applicability to the clinical question and if the outcomes were patient oriented, and also if they were relevant to my topic of interest.

The inclusion criteria of my search consisted of whether the study researched type 2 diabetes, and if the study measured balance using the Timed Up And Go test. The exclusion criteria were if the study focused on type 1 diabetes and balance was measured using another method than the TUG test. All three articles evaluated the treatment effect using the mean change in baseline, as well as p values to analyze and report data. Table 1 shows the demographics and characteristics of the included studies.

OUTCOMES MEASURED

The outcome measured was balance, which was evaluated using the Timed Up and Go Test. This test consists of measuring the amount of time it takes a person to get up from a seated position in a chair, walk three meters, turn around, walk back and sit down again. The timed up and go test is considered to be an accurate evaluation of balance.⁷

RESULTS

All studies included adults with type 2 diabetes mellitus with mild to moderate neuropathy that were diagnosed using the American Diabetes Association diagnostic criteria. The studies by Del Pozo-Cruz et al.⁷ and Kordi Yoosefinejad et al. 2014⁸ were randomized controlled trials that compared the treatment effects of receiving whole body

vibration therapy to a control group that received no intervention. The study by Kordi Yoosefinejad et al. 2015⁹ was a case series that measured the patient's improvement before and after receiving the vibration treatment without comparison to an untreated control group.

The study by Del Pozo-Cruz et al. used mean change from baseline to evaluate the results of the intervention. The change in scores from baseline showed a between group difference of -1.27 seconds to 0.38 seconds, which results in a mean change of -0.44 seconds (Table 2). However, although these numbers represent a decrease in time of the TUG in the intervention group, the results were not significant (p value= 0.273). Therefore, this study did not show a statistically significant improvement in the TUG test and balance after receiving WBV therapy.⁷

The study by Kordi Yoosefinejad et al. 2014 also measured improvement by recording the mean change in baseline of the two groups in their TUG test time. The intervention group had an average time of 9.3 +/- 0.8 seconds, while the control group had an average time of 9.15 +/- 0.4 seconds. This leads to a treatment effect size of -0.83 seconds. The p value was 0.002 (Table 2). This study shows a statistically significant improvement in balance in the group receiving WBV therapy.⁸

The study by Kordi Yoosefinejad et al. 2015 measured improvement by recording the mean change in baseline on the seconds of the TUG test on the same group of 10 participants before and after receiving WBV therapy. Before receiving the treatment, the average time was 8.51 +/- 1.6 seconds. After receiving WBV therapy, the average for the TUG test was 7.77 +/- 1.1. This leads to a mean change in baseline of

-0.74 seconds, and a p value of 0.004 (Table 2). This shows that there was a statistically significant improvement in the TUG test after receiving WBV therapy.⁹ This improvement in seconds, although small, can make a difference in the balance and overall well being of patients with diabetic neuropathy.

Table 2- Summary Of Results

Study	Control group (mean +/- SD) secs	Intervention group (mean +/- SD) secs	Mean change from baseline (secs)	p- value
Del Pozo-Cruz ⁷ (2013)	-1.27	0.38	-0.44	0.273
Kordi Yoosefinejad ⁸ (2015)	9.3 +/- 0.8	9.15 +/- 0.4	-0.80	0.002
Kordi Yoosefinejad ⁹ (2014)	8.51 +/- 1.6 (before treatment)	7.77 +/- 1.1 (after treatment)	-0.74	0.004

The studies were all conducted in an outpatient, primary care setting in diabetic patients with mild to moderate neuropathy. Del Pozo-Cruz et al. excluded participants with advanced cardiovascular, renal, or hepatic disease, diabetic retinopathy, nephropathy or neuropathy, insulin use, or any other co-existing health problems that would interfere with the patient's ability to exercise safely. They also excluded individuals receiving physical therapy for their neuropathy as it would confound the results of using WBV.⁷ Kordi Yoosefinejad et al. 2014 excluded participants with epilepsy, cognitive disorders, prosthesis, pacemakers, or gallstones as these are contraindications to receiving whole body vibration therapy.⁸ There were no reported adverse events or safety concerns associated with receiving WBV therapy in any of the trials.

DISCUSSION

Although the research by Del Pozo-Cruz et al. did not show statistically significant results, the researchers possibly attributed this due to their difference in instructions given to participants for the Timed Up and Go test. Instead of the standard instructions of “walk at a regular pace,” subjects were instructed to “walk as quickly as possible.” This slight difference in instructions may explain why the study found no improvement in balance between the groups.⁷ Even though the results did not find significance on WBV therapy improving balance in type 2 diabetics, this study mentions that there have been other studies that show that WBV therapy does improve balance in the elderly.⁷

There are some limitations to my search criteria, as I only searched the PubMed and Google Scholar databases. There may be more articles about this topic on other databases as well as ones that do not include the keywords that were searched. The sample sizes of the studies were also limited, as they only included 39, 20, and 10 participants. Due to the nature of the intervention, these studies were all single blind rather than double blind, as the participants were aware if they were receiving the intervention of WBV therapy. Therefore, some of the improvement seen in the participants who received the treatment may be a result of the placebo effect. Although they included different subjects and were different types of studies, two of the studies were conducted by the same team of researchers, which may affect the generalizability of the results.

The use of whole body vibration therapy is new, but many studies are being conducted to test its effects on treating a variety of illnesses. Vibrating boards are used in the fitness community to improve endurance and increase performance and muscle

strength in athletes. It is also used for improving balance and reducing falls in the elderly, reducing fractures and increasing bone density associated with osteoporosis, and reducing back pain. New research shows that whole body vibration may have a role in helping with symptoms of fibromyalgia, multiple sclerosis, Parkinson's disease, and rheumatoid arthritis, as well as others.¹⁰

Like any therapy, there may be adverse effects if the treatment is used incorrectly or inappropriately. Vibration, in excess, can cause harm to the body. This is usually not a concern when the therapy is given under direct supervision of a medical provider who can control the frequency and time on the board. It becomes an issue when home vibration boards or ones found at community gyms are unregulated and may be overused. Excessive use of vibration may cause brain damage, blurred vision, and hearing loss. Even though it can help reduce back pain, overuse can also lead to back pain by causing muscle strain and injury to ligaments.¹¹ Whole body vibration therapy may not be appropriate for every patient. Contraindications to receiving whole body vibration therapy include pregnancy, deep vein thrombosis, vertigo, severe diabetic neuropathy, tumors, epilepsy, gall/kidney/bladder stones, cardiac arrhythmias, and pacemakers or cardiac stents.¹²

CONCLUSION

The research on whether or not whole body vibration therapy improves balance in patients with type 2 diabetes is inconclusive. Two studies showed a statistically significant improvement in balance after the treatment, while one did not (Table 2). Further research should be conducted to determine the true benefit of this intervention.

There are many avenues for future research of this topic, as the studies included were inconsistent with the administration of the intervention. Del Pozo-Cruz et al. gave WBV therapy using a frequency of 16 Hz of vibration, three times a week for 12 weeks.⁷ Kordi Yoosefinejad et al. 2014 used a frequency of 30 Hz of vibration, twice per week for six weeks.⁸ Kordi Yoosefinejad et al. 2015 gave participants a one time treatment with a vibration frequency of 30 Hz.⁹ Further research should be conducted to determine what the most optimal treatment regimen of hertz of vibration and duration and frequency of treatment is that provides the most benefit to the patient without causing harm to patients. Additionally, these studies also only carried out the treatment for a maximum of 12 weeks, and it is unclear if a further benefit would result if the treatment was continued for a longer period of time. There was also no follow up after these treatments to see if the improvements in balance were long-term or temporary. It would also be beneficial to conduct a study to see if there is a reduction in the number of falls a person has after having received the treatment. Whole body vibration therapy has the potential to be a beneficial treatment for improving balance in patients with type 2 diabetes and neuropathy, but further studies need to be conducted to determine its true efficacy and the most beneficial treatment regimen.

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